REMARKS

Applicants have amended claim 1 to improve its form and to more clearly point out the claimed subject matter. The amendment does not introduce new matter. Upon entry of the amendment, claims 1, 10-16, 19, 20, 22-25, 27, 31-33, 35-41, 43-46, 48, 52, 53, 55-59, 61-72, 74, 78, 85, 88, 90, 91, 94, 97, 102, 104, 107, 109,-112, 114-116, 119-123, 133, and 135-139 are pending in the application. Applicants request entry of the amendment and reconsideration of the claims.

Disposition of Claims

Applicants note some discrepancies in the Disposition of Claims and wish to confirm the pending claims. Applicants filed the present application, which included claims 1-139, on July 25, 2003 along with a Preliminary Amendment. The Preliminary Amendment, *inter alia*, canceled claims 2-9, 17-18, 21, 26, 28-30, 34, 42, 47, 49-51, 54, 60, 73, 75-77, 79-84, 86-87, 89, 92-93, 95-96, 98-101, 103, 105-106, 108, 113, 117, 124-132, and 134 (without prejudice). Accordingly, claims 1, 10-16, 19, 20, 22-25, 27, 31-33, 35-41, 43-46, 48, 52, 53, 55-59, 61-72, 74, 78, 85, 88, 90, 91, 94, 97, 102, 104, 107, 109, 112, 114-116, 118-123, 133, and 135-139 are pending in the application. More specifically, the Disposition of Claims incorrectly indicates that claim 28 is pending and does not include claims 48 and 56-59 among the pending claims.

Election/Restrictions

As noted by the Examiner, applicants have elected, with traverse, Group I relating to "an isolated antibody that binds the V1/V2 loop and is dependent on the presence of a sequence in the V1 loop" (claims 1, 10-16, 22 and 23). In the June 29, 2006 Office Action, which was a requirement for restriction, the Examiner indicated that claims 53, 55, 69, 70, 85, 88, 90, 91, 94, 97, 102, 104, 107 and 139 were generic claims that would be examined along with Group I, if elected.

Applicants note that at least pending claims 52 and 78 appear not to have been included in any proposed Group. Claim 52 depends in part from claim 1 and is directed to an isolated human

antibody or antigen-binding portion thereof where the antibody or portion has HIV-1 neutralizing activity *in vivo*. Claim 78 depends in part from claim 16, an elected claim, and is directed to an isolated human antibody or antigen-binding portion thereof wherein the antibody is an IgG, and IgM, an IgE, an IgA or an IgD molecule or is derived therefrom. Applicants believe that claims 52 and 78 should have been examined with the claims of elected Group I but it does not appear that they were. Accordingly, applicants request that further examination of the claims, if any, include those claims and that an Office Action issued as a result of further examination, if any, be a non-final office action to permit applicants to sufficient opportunity to respond, if necessary.

In summary, applicants believe that claims 1, 10-16, 22, 23, 52, 53, 55, 69, 70, 78, 85, 88, 90, 91, 94, 97, 102, 104, 107 and 139 are under examination in this application and that claims 19, 20, 24, 25, 27, 31-33, 35-41, 43-46, 48, 56-59, 61-68, 71, 72, 74, 109-112, 114-116, 118-123, 133 and 135-138 are pending and withdrawn.

Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 19, 20, 22 and 23 stand rejected under 35 U.S.C. § 112, first paragraph (enablement). Specifically, in the Examiner's view, for enablement, applicants must provide assurances regarding the extent of public availability of the antibody produced by the cell line having ATCC accession number PTA-3002. According to the Examiner, a statement that the deposit was made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent would satisfy the deposit requirement.

Applicants enclose herewith a Statement of the undersigned providing the required assurances. Accordingly, the rejection under § 112, first paragraph, should be withdrawn.

Rejections Under 35 U.S.C. § 102(a)

Claims 1, 10-14, 16, 53, 55, 69, 70, 85, 88, 90, 91, 97, 102, 104, 107 and 139 stand rejected under 35 U.S.C.§ 102(a) as "anticipated" by D.R. Burton et al., "Efficient Neutralization of Primary Isolates of HIV-1 by a Recombinant Human Monoclonal Antibody," *Science* 266: 1024-1027

(1994) ("Burton"). According to the Examiner, Burton "teaches" neutralizing recombinantly made monoclonal antibodies that neutralize various isolates of HIV, bind at the CD4 binding site and compete with other antibodies. In the Examiner's view, such antibodies appear to meet the limitations of the claims. In view of the claim amendment, applicants traverse.

Claim 1, and claims 10-14, 16, 53, 55, 69, 70, 85, 88, 90, 91, 97, 102, 104, 107 and 139, which depend directly or indirectly from claim 1, is directed in pertinent part to an isolated human antibody or antigen-binding portion thereof that recognizes an epitope in the V1 loop or domain of HIV-1 gp120. Burton does not disclose such an antibody.

Instead, as correctly noted by the Examiner, Burton refers to antibodies that bind HIV gp120, including an antibody, b12, that is said to be a human antibody. According to Burton, b12 recognizes an epitope in the CD4 binding site of HIV gp120 (page 1024, right column). The claims, thus, are novel over Burton.

Claims 1, 10-14, 16, 53, 55, 69, 70, 85, 88, 90, 91, 97, 102, 104, 107 and 139 also stand rejected under 35 U.S.C. § 102(a) as "anticipated" by A. Pinter et al."Potent Neutralization of Primary HIV-1 Isolates by Antibodies Directed Against Epitopes Present in the V1/V2 Domain of HIV-1 gp120," *Vaccine*, 16: 18031811 (Pinter"). According to the Examiner, Pinter "teaches" neutralizing antibodies to various isolates of HIV that bind an epitope in the V1/V2 domain. In the Examiner's view, such antibodies appear to meet the limitations of the claims. In view of the claim amendment, applicants traverse.

The subject matter of the claims is described above and relates to neutralizing human antibodies that bind an epitope in the V1 domain of HIV gp120. Pinter refers to a number of monoclonal antibodies that bind the CD4 binding site, the V2 domain, the V3 domain or a conformational epitope of HIV gp120 or that bind to gp41. Pinter also refers to antibodies from HIV infected patients that were isolated by binding to the V1/V2 domain of gp120 from the Case-A2 strain of HIV. In contrast, as disclosed in the application, as filed, the V1-specific antibodies did not bind the V1/V2 domain of Case-A2. See page 101, line 30 to page 102, line 14. The claims, thus, are novel over Pinter.

In view of the above, applicants request withdrawal of the rejections under § 102.

Rejections Under 35 U.S.C. § 103

Claims 1, 10-16, 22, 23, 53, 55, 69, 70, 85, 88, 90, 91, 97, 102, 104, 107 and 139 stand rejected under 35 U.S.C. § 103(a) as "unpatentable" over United States patent 5,643,756 (Kayman et al.) ("Kayman"). According to the Examiner, Kayman "teaches" that antibodies to the V2 loop are neutralizing, provides a construct that displays the V1/V2 loop in a conformationally correct way and that any sequence of a known strain can be used in this construct. The Examiner concludes that one of ordinary skill in the art would have been able to make neutralizing antibodies to V1/V2 loops of gp120 of any known strain, that because the construct used in Kayman included a V1 loop, the V1 loop is required to make the antibody so that it would have been obvious to make a neutralizing antibody that recognizes an epitope on the V1/V2 domain. In view of the claim amendment, applicants traverse.

As noted previously, the claims relate to a human neutralizing antibody that recognizes an epitope in the V1 domain of HIV gp120. Kayman refers to a neutralizing epitope in the V2 domain of gp120 and to a neutralizing monoclonal antibody that binds a V2 domain epitope. Applicants did not find a reference to a neutralizing human antibody that recognizes an epitope in the V1 domain of HIV gp120. Accordingly, the claims cannot be obvious over Kayman. Accordingly, applicants request withdrawal of the rejection under § 103.

Double Patenting

Claims 1, 10-13, 15, 16, 22, 23, 53, 55, 69, 70, 85, 88, 90, 91, 97, 102, 104, 107 and 139 stand rejected under the non-statutory obvious-type double patenting as "unpatentable" over claims 19-20 of United States patent 6,815,201 (Pinter) ("Pinter 2"). In view of the claim amendment, applicants traverse.

Applicants have described the subject matter of the claims previously. Claim 19 of Pinter 2 is directed to a monoclonal antibody that binds the gp120 V1/V2 domain of HIV-1 strain Case-A2 and neutralizes at least one clade B HIV-1 primary isolate with a ND90 of less than 100 μg/ml. Claim 20, which depends from claim 19, adds that the antibody neutralizes at least one clade A

HIV-1 primary isolate with a ND90 of less than 100 μg/ml. Neither of the claims refers to a human neutralizing antibody that recognizes an epitope in the V1 domain. The claims, thus, are not obvious over Pinter 2. Applicants request withdrawal of the rejection for non-statutory obviousness-type double patenting.

Conclusion

In view of the foregoing, applicants request withdrawal of the rejections and reconsideration of the pending claims.

Respectfully submitted,

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